UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA *ex rel.* RICHARD TEMPLIN AND JAMES BANIGAN, *et al.*, Plaintiffs, vs. ORGANON USA INC., *et al.*, Defendants.	Civil Action No. 07-12153-RWZ

MEMORANDUM OF LAW IN SUPPORT OF OMNICARE, INC.'S MOTION TO RECONSIDER THE COURT'S AUGUST 23, 2016 ORDER OR, IN THE ALTERNATIVE, TO CERTIFY THE MATTER FOR INTERLOCUTORY APPEAL PURSUANT TO 28 U.S.C. § 1292(b)

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Omnicare, Inc. ("Omnicare") respectfully submits this Memorandum of Law in support of its Motion to reconsider or, in the alternative, to certify pursuant to 28 U.S.C. § 1292(b) for immediate interlocutory appeal to the United States Court of Appeals for the First Circuit this Court's Order on Omnicare's motions for summary judgment, entered August 23, 2016 (Dkt. No. 485) (the "Order").

PRELIMINARY STATEMENT

In its Order, the Court denied Omnicare's and the Acquired Pharmacies'[1] motions for summary judgment, concluding that there is a genuine factual dispute about whether the discounts and rebates that Omnicare and the Acquired Pharmacies received for Remeron tablet and Remeron SolTab fell within the regulatory discount safe harbor, 42 C.F.R. § 1001.952(h)(1)(iii) (the "RDSH").[2] Although the Court found that Omnicare had satisfied the RDSH's first element—that the discounts were "'made at the time of the sale,' and 'fixed and disclosed in writing . . . at the time of the initial sale,'" Order at 9 (quoting 42 C.F.R. § 1001.952(h)(1)(iii))—it held that Omnicare failed to satisfy the RDSH's second element—that "the provider furnishes, 'upon request by the Secretary or a State agency,' documentation both of the discount and that provider's awareness of its obligation to report it." *Id*. Specifically, the Court found that the RDSH did not apply because Omnicare had not shown that it "made the relevant disclosures pursuant to a governmental investigation, as the parties agree that no such

[1] The "Acquired Pharmacies" are American Pharmaceutical Services, Inc. ("APS"); SunScript Pharmacy Corporation ("SunScript"); NCS HealthCare, Inc. ("NCS"); and NeighborCare, Inc. ("NeighborCare"). The Court granted summary judgment dismissing the claims against APS and SunScript, on grounds not relevant to this Motion. *See* Order at 5, 13.

[2] Although Omnicare and the Acquired Pharmacies do not agree with the other rulings by the Court and reserve their rights to appeal the denial of their motions for summary judgment on all other grounds at the appropriate time, the current Motion only seeks reconsideration or certification of the narrow legal question of the proper interpretation of the RDSH.

investigation took place during the relevant period." *Id*. at 10. In so holding, the Court found that "government action" is a "necessary condition" of the RDSH. *Id*.

For the reasons demonstrated below, Omnicare respectfully requests that the Court reconsider or certify for immediate interlocutory appeal its finding that, as a matter of law, a charge-based provider such as Omnicare cannot satisfy the RDSH where the government did not make a request for documentation of the discounts and rebates.

First, granting reconsideration of the Order is in the interests of justice. The plain language of the RDSH requires a buyer to provide the specified information only "upon request" by the government. 42 C.F.R. § 1001.952(h)(1)(iii)(B). In other words, the RDSH's requirement that a buyer provide the specified information is triggered only *if* the government actually makes a request for the information referenced in the RDSH, and the buyer loses the RDSH's protection only if it refuses to comply with such a request. Nonetheless, in ruling on the motions for summary judgment, the Court interprets the RDSH to require "government action" as a "necessary condition" of the RDSH in the first instance. Order at 10. Omnicare is aware of no First Circuit or other authority or Department of Health and Human Services Office of Inspector General ("OIG") guidance construing the RDSH in this manner. In addition, such a construction of the RDSH would render it impossible for any buyer to accept discounts or rebates with any confidence of their lawfulness, because at the time the discounts or rebates are offered the government will not have requested the disclosure of the discount or rebate agreements. The Court's interpretation therefore effectively eviscerates the RDSH for buyers and cannot be what the OIG intended in promulgating the RDSH. Accordingly, reconsideration of the Order is in the interests of justice.

Second, because all of the statutory requirements for immediate interlocutory appeal are

met here, this Court at a minimum should amend its Order to include the necessary certification for interlocutory appeal pursuant to 28 U.S.C. § 1292(b).[3] Whether "government action" is a "necessary condition" for a charge-based provider such as Omnicare to be entitled to the protections of the RDSH, Order at 10, is a pure, controlling question of law, and its resolution in Omnicare's favor would materially advance the termination of the litigation. Indeed, because the Court found that Omnicare has satisfied the first element of the RDSH, *see id*. at 9, if the First Circuit were to accept Omnicare's position that the RDSH does not require "government action" before the RDSH can apply, it necessarily would mean that the discounts and rebates at issue satisfy the RDSH. In that event, Omnicare would be entitled to summary judgment and the litigation would be terminated.

Moreover, the legal question of whether the RDSH is satisfied even where there has been no "government action" is one that is both subject to a substantial ground for dispute and carries broad importance beyond this particular case. This Court's Order appears to be the first time that any court has addressed the question of whether the RDSH is satisfied where, as here, the discounts and rebates were made at the time of sale and fixed in writing but neither the "Secretary [n]or a State Agency" made a "request" for the relevant "documentation." 42 C.F.R. § 1001.952(h)(1)(iii). Neither the plain language of the RDSH nor any prior judicial precedent compelled the Court's construction of the RDSH. As the only judicial precedent on this critical issue, the Court's construction of the RDSH may very well discourage charge-based providers such as Omnicare from negotiating and accepting discounts and rebates from pharmaceutical manufacturers, which ultimately will hurt the healthcare system as a whole by raising the price of

[3] The Order may be amended to include the necessary certification at any time while the litigation proceeds. *See* Fed. R. Civ. P. 54(b); *see also* Fed. R. App. P. 5(a)(3) ("the district court may amend its order, either on its own or in response to a party's motion, to include the required permission or statement").

drugs. Given this heightened level of systemic importance, it is critical that the First Circuit be allowed to weigh in on this issue sooner rather than later.

ARGUMENT

I. GIVEN THE PLAIN LANGUAGE OF THE RDSH, THE LACK OF CONTROLLING AUTHORITY INTERPRETING THE RDSH TO REQUIRE "GOVERNMENT ACTION," AND THE IMPLICATIONS OF THE COURT'S INTERPRETATION, THE COURT SHOULD RECONSIDER ITS ORDER DENYING OMNICARE'S MOTION FOR SUMMARY JUDGMENT.

Although the Court agreed that Omnicare satisfied the first requirement of the RDSH, it denied Omnicare's motion for summary judgment because it found that Omnicare failed to demonstrate that it had satisfied the RDSH's second requirement. In support of its argument that all of the requirements of the RDSH had been met in this case, Omnicare demonstrated in its Motion for Summary Judgment that during the relevant time period, neither Omnicare nor the Acquired Pharmacies received a request from the government for the information specified in the RDSH. *See* Order at 10. Omnicare's argument was based on its understanding of the plain language of the RDSH that a buyer's obligation to provide the information referenced in the RDSH is triggered only if there has been a "*request* by the Secretary or a State agency" for that information. 42 C.F.R. § 1001.952(h)(1)(iii)(B) (emphasis added). Absent such a request, there is nothing to which the RDSH requires a response and therefore, a buyer need only satisfy the RDSH's first requirement (*i.e.*, that the discount is made at the time of the sale and is fixed and disclosed in writing) in order for the RDSH to protect the discounts and rebates at issue.[4] The Court, however, held that "government action" is a "necessary condition" for application of the

[4] *See* Mem. of Law in Support of Omnicare's Mot. for Summary Judgment (Dkt. No. 415) at 15 ("Relators cannot argue that Omnicare or the Acquired Pharmacies failed to provide the documentation specified in the RDSH to satisfy the provision's second requirement *because that requirement is trigged only 'upon request by the [HHS] Secretary or a State agency*.'" (quoting 42 C.F.R. § 1001.952(h)(1)(iii)) (emphasis added)).

RDSH and found that Omnicare failed to satisfy this second element of the RDSH because Omnicare could not show that it "made the relevant disclosures pursuant to a governmental investigation" because no such request was made during the relevant time period. Order at 10. Given the plain language of the RDSH, the lack of controlling authority supporting the Court's interpretation, and the untenable results that would arise from such an interpretation—including the complete evisceration of the RDSH for buyers such as Omnicare—Omnicare respectfully submits that reconsideration of the Court's Order finding that "government action" is a "necessary condition" for the application of the RDSH merits reconsideration in the interests of justice.

District courts have "the inherent power . . . to afford . . . relief from interlocutory judgments . . . as justice requires." *Greene v. Union Mut. Life Ins. Co. of Am.*, 764 F.2d 19, 22 (1st Cir. 1985) (internal quotation marks and citation omitted). "When faced with a motion to reconsider, the district court must apply an interests-of-justice test." *Douglas v. York County*, 360 F.3d 286, 290 (1st Cir. 2004). Reconsideration of an interlocutory order may also be warranted where a movant demonstrates "(1) an intervening change in the law; (2) the discovery of new evidence not previously available; or (3) a clear error of law in the first order." *Davis v. Lehane*, 89 F. Supp. 2d 142, 147 (D. Mass. 2000). Moreover, "[i]n determining whether reconsideration is warranted, courts often consider whether the court has patently misunderstood the parties or made an error of apprehension, whether the parties have proffered supplemental evidence or new theories not previously before the court, or whether the decision was outside the issues presented to the court by the parties." *Flynn v. Dick Corp.*, 620 F. Supp. 2d 33, 38 (D.D.C. 2009). "Ultimately, however, 'asking what justice requires amounts to determining, within the Court's discretion, whether reconsideration is necessary under the relevant

circumstances.'" *Id.* (quoting *Cobell v. Norton*, 355 F. Supp. 2d 531, 539 (D.D.C. 2005)). Here, granting Omnicare's request for reconsideration is in the interests of justice.

As an initial matter, Omnicare is aware of no First Circuit authority, OIG guidance, or statutory or regulatory rulemaking history that interprets the RDSH in this manner.[5] Nothing in the RDSH suggests that a "governmental investigation" or other "government action" is a necessary prerequisite to be entitled to protection under the RDSH. Rather, the plain language of the regulation states that a buyer must provide an "invoice, coupon or statement" from the seller that "fully and accurately" reports the discount or rebate only if a request is made by the government:

> The buyer (if submitting the claim) must provide, *upon request* by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(iii)(B) of this section,[6] or information provided by the offeror as specified in paragraph (h)(3)(iii)(A) of this section.[7]

42 C.F.R. § 1001.952(h)(1)(iii)(B) (emphasis added). Nowhere does the regulatory text or the regulatory history indicate that discounts and rebates can be protected by the RDSH only if the government in fact makes a disclosure request. Simply put, the RDSH imposes an obligation on the buyer to provide the enumerated information only *if* a request for such information is made.

In fact, the rulemaking history of the RDSH undercuts an interpretation of this second element requiring a government investigation in order for a charge-based buyer such as

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[5] Omnicare also is not aware of any Circuit or District Court to have interpreted the RDSH in this manner.

[6] Section 1001.952(h)(2)(iii)(B) provides: "Where the buyer submits a claim, the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph."

[7] Section 1001.952(h)(3)(iii)(A) provides: "The offeror must inform the individual or entity submitting the claim or request for payment in a manner reasonably calculated to give notice to the individual or entity of its obligations to report such a discount and to provide information upon request under paragraphs (h)(1) and (h)(2) of this section."

Omnicare to be entitled to the protections of the safe harbor. As explained in Omnicare's Rule 56.1 Statement of Undisputed Material Facts in Support of Its Motion for Summary Judgment (Dkt. No. 416) ("SUF"), the version of the RDSH promulgated in 1991 required affirmative disclosure of discounts, providing that, for charge-based buyers (such as Omnicare and the Acquired Pharmacies), a discount had to be reported on the claim submitted for payment if it was a separately reimbursable item. *See* SUF ¶ 80. Specifically, the 1991 RDSH imposed the following requirements upon charge-based buyers:

> (A) the discount must be made at the time of the original sale of the good or service;
>
> (B) where an item or service is separately claimed for payment with the Department or a State agency, the buyer must fully and accurately report the discount on that item or service; and
>
> (C) the buyer must provide, upon request by the Secretary or a State agency, information provided by the seller as specified in paragraph (h)(2)(ii)(A) of this section.

42 C.F.R. § 1001.952(h)(1)(iii) (1991); *see also* SUF ¶ 80. Thus, the 1991 RDSH required that a charge-based buyer both disclose the discount or rebate when submitting a claim for payment and provide the specified information in the event a request was made by the government. The RDSH was amended and expanded in November 1999. Significantly, the OIG recognized that charge-based buyers do not have a mechanism to disclose discounts and rebates in the ordinary course, and explained that, among other amendments, "[w]e are eliminating the requirement that charge-based buyers report discounts on claims submitted to the Federal programs; however, we are retaining the requirement that such buyers provide documentation of discounts to the Secretary *upon request*." Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63518, 63527 (Nov. 19, 1999) (to be codified at 42 C.F.R. pt.

1001) (emphasis added); *see also* SUF ¶ 81. The 1999 amendments further expanded the RDSH by modifying the definition of "rebate" to extend safe harbor protection to certain charge-based buyers.[8] Interpreting 42 C.F.R. § 1001.952(h)(1)(iii)(B) to require a government investigation in order for the RDSH to apply would render meaningless the 1999 amendments, which expanded charge-based buyers' ability to accept discounts and rebates and fall within the RDSH, as it would prevent the RDSH from protecting discounts and rebates to charge-based buyers who did not receive a request for information from the Secretary or a State agency.[9]

Moreover, the Court's construction of the second element of the RDSH to require "government action" would eviscerate the RDSH and render it entirely meaningless for buyers. Under the Court's interpretation, if a buyer entered into an agreement with a manufacturer that includes a discount or rebate, the receipt of that discount or rebate is presumptively a "kickback" and thus a potential predicate for criminal prosecution and/or a False Claims Act action unless and until that buyer receives a government request for information and the buyer responds to that request. The practical effect of this would be that as soon as a buyer agrees to accept discounts and rebates, it is in violation of the law because the RDSH cannot protect such discounts and rebates in the absence of a government request for information. Needless to say, at the time a buyer is offered discounts or rebates, it would have no way of knowing whether the government will eventually request information regarding those discounts and rebates. Thus, under the

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[8] *See* 64 Fed. Reg. 63518, 63527 (Nov. 19, 1999) ("We are modifying our proposed definition of a 'rebate' to include any discount the terms of which are fixed at the time of the sale of the good or service and disclosed to the buyer, but which is not received at the time of the sale of the good or service. This modification will enable us to extend safe harbor protection to certain charge-based buyers and buyers reimbursed on the basis of fee schedules who obtain rebates."); *see also* SUF ¶ 81.

[9] In addition, given the plain regulatory language and rulemaking history, it is "not objectively unreasonable," Order at 8, for a charge-based buyer such as Omnicare to believe that it must only make the specified disclosures if a request is received and that it can still qualify for the RDSH absent a government request as long as it satisfies the RDSH's first requirement.

Court's interpretation, the only way for a buyer to comply with the law would be to reject any and all offers of discounts and rebates. In other words, it would be impossible for buyers to accept any discount or rebate without being in violation of the law. This result would be contrary to the purpose behind the RDSH, as acknowledged by the OIG in promulgating the 1999 RDSH, of "encourag[ing]" discounts for health care items and services under the Federal health care programs. 64 Fed. Reg. 63518, 63526 (Nov. 19, 1999).

Moreover, the Court's interpretation would require the government to take action to investigate every buyer receiving a discount or rebate, in order to make the RDSH protection potentially available to buyers. In fact, in a statement of interest recently filed by the United States in another case pending before this Court, the government essentially conceded that a buyer can qualify for protection under the RDSH absent a request by the Secretary or a State agency. *See* United States' Statement of Interest Regarding Plaintiff's Motion for Reconsideration of the Court's Dismissal of CCS at 3, *United States ex rel. Herman v. Coloplast Corp.*, No. 11-12131-RWZ (D. Mass.), filed Aug. 8, 2016 (Dkt. No. 170) ("If CCS [a buyer] and Coloplast [a seller] simply agreed to a pricing structure that offered escalating discounts in return for increased sales, and CCS then independently (not pursuant to an agreement with Coloplast) relied on certain 'hard' and 'soft' sales tactics to achieve the increased sales, then the United States agrees that such an arrangement would qualify as a 'discount' and therefore would not violate the AKS.").

In addition, interpreting the RDSH to require a government investigation in order for a buyer to be entitled to the protections of the safe harbor would lead to different results depending on whether the party to the discounts and rebates is a buyer or a seller. Specifically, a seller providing the discount to the buyer would qualify for protection under the RDSH, but the buyer

receiving that same discount would not be able to qualify absent a government disclosure request because only the buyer is required to disclose certain information "upon request" by the government.[10] Moreover, the Court's interpretation would lead to different treatment of buyers receiving the exact same discount based solely on whether the buyer happened to receive a government disclosure request. It would be an odd result for the RDSH to protect the seller but not the buyer, or to protect only certain buyers depending on the fortuity of whether the buyer happened to receive a government disclosure request, when the same exact discount or rebate agreement is at issue.

Accordingly, for all of these reasons, Omnicare respectfully submits that the interests of justice merit reconsideration of the Court's Order finding that the RDSH did not apply to protect the discounts and rebates at issue because "government action" is a "necessary condition" for the application of the RDSH.

II. IN THE ALTERNATIVE, INTERLOCUTORY APPEAL OF THIS COURT'S ORDER HOLDING THAT "GOVERNMENT ACTION" IS A "NECESSARY CONDITION" FOR THE APPLICATION OF THE RDSH IS APPROPRIATE UNDER SECTION 1292(b).

Under Section 1292(b), a district court has discretion to certify an interlocutory order for immediate appeal if the following three requirements are met: the order presents (i) a "controlling question of law," (ii) over which there is a "substantial ground for difference of opinion," and (iii) an immediate appeal will "materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b); *see also Philip Morris Inc. v. Harshbarger*, 957 F. Supp. 327,

[10] *See* 42 C.F.R. § 1001.952(h)(2)(iii)(B) (In order for a seller to qualify for protection under the RDSH, "[w]here the buyer submits a claim [the situation at issue in this case], the seller must fully and accurately report such discount on the invoice, coupon or statement submitted to the buyer; inform the buyer in a manner reasonably calculated to give notice to the buyer of its obligations to report such discount and to provide information upon request under paragraph (h)(1) of this section; and refrain from doing anything that would impede the buyer from meeting its obligations under this paragraph.").

330 (D. Mass. 1997) ("Under 28 U.S.C. § 1292(b), a district judge may certify for interlocutory appeal an order, not otherwise appealable, that involves a controlling question of law as to which there is substantial ground for difference of opinion, where an immediate appeal may materially advance the ultimate termination of the litigation."); *Camacho v. Puerto Rico Ports Auth.*, 369 F.3d 570, 573 (1st Cir. 2004) (same; granting interlocutory appeal); *Tr. of Boston Univ. v. Epistar Corp.*, No. 12-11935-PBS, 2016 WL 4238554, at *1 (D. Mass. Aug. 9, 2016) (same; granting motion to amend order to permit interlocutory appeal); *Plumbers' Union Local No. 12 Pension Fund v. Nomura Asset Acceptance Corp.*, 894 F. Supp. 2d 144, 157 (D. Mass. 2012) (same; "[w]hile interlocutory appeals are granted 'sparingly and only in exceptional circumstances,' this court is of the opinion that this is one of those 'rare cases [that] qualif[ies] for the statutory anodyne'" (citation omitted)); *Lawson v. FMR LLC*, 724 F. Supp. 2d 167, 169 (D. Mass. 2010) (same; granting motion for certification); *Reynolds v. U.S. Internal Revenue Serv.*, No. 13-10788-NMG, 2014 WL 201610, at *1-2 (D. Mass. Jan. 15, 2014) (applying same requirements in granting motion for leave to file interlocutory appeal in bankruptcy proceeding). As a leading commentator has explained:

> the three factors that justify interlocutory appeal should be treated as guiding criteria rather than jurisdictional requisites. Section 1292(b) is best used to inject an element of flexibility into the technical rules of appellate jurisdiction established for final-judgment appeals under § 1291 and for interlocutory appeals under § 1292(a). The three factors should be viewed together as the statutory language equivalent of a direction to consider the probable gains and losses of immediate appeal.

16 Charles Alan Wright, *et al.*, Federal Practice and Procedure § 3930 (3d ed. 1998) ("Federal Practice"). Moreover, although courts have recognized that certification under Section 1292(b) should be used sparingly, "[i]t is equally important . . . to emphasize the duty of the district court and of [the Court of Appeals] as well to allow an immediate appeal to be taken when the

statutory criteria are met." *Ahrenholz v. Bd. of Tr. of Univ. of Ill.*, 219 F.3d 674, 677 (7th Cir. 2000).

As demonstrated below, the Court's Order involves a controlling question of law, namely, whether the request by the Secretary or a State agency referenced in the RDSH applicable to buyers, 42 C.F.R. § 1001.952(h)(1)(iii), is a necessary condition to the application of the RDSH, such that if no such request is made during the relevant time period, the discounts and rebates received by the buyer cannot be protected by the RDSH. In addition, there is substantial ground for difference of opinion over the answer to that question and that question carries broad importance beyond this particular case. Finally, there are significant "probable gains" from an immediate appeal of the question because a reversal of the Court's decision on this issue will obviate the need for a lengthy and costly trial and terminate the litigation. Accordingly, all of the statutory requirements for an interlocutory appeal under Section 1292(b) are met here.

A. The Court's Order Interpreting The RDSH Involves A "Controlling Question Of Law" And An Immediate Appeal Will "Materially Advance The Termination Of The Litigation."

The requirements that the Order present a "controlling question of law" and that an immediate appeal will "materially advance the ultimate termination of the litigation" are easily satisfied here. As courts have explained, "a controlling question of law usually involves 'a question of the meaning of a statutory or constitutional provision, regulation, or common law doctrine' rather than an application of law to the facts." *So. Orange Chiropractic Ctr., LLC v. Cayan LLC*, No. 15-13069-PBS, 2016 WL 3064054, at *2 (D. Mass. May 31, 2016) (quoting *Ahrenholz*, 219 F.3d at 676); *see also id*. ("'[W]hat the framers of § 1292(b) had in mind is more of an abstract legal issue or what might be called one of pure law, matters the court of appeals

can decide quickly and cleanly without having to study the record.'" (quoting *McFarlin v. Conseco Servs., LLC*, 381 F.3d 1251, 1258 (11th Cir. 2004))). Moreover, a question of law is "controlling" if "reversal of the district court's order would terminate the action." *Philip Morris*, 957 F. Supp. at 330 (internal quotation marks and citation omitted); *see also id*. (citing *Arizona v. Ideal Basic Indus. (In re Cement Antitrust Litig.)*, 673 F.2d 1020, 1026 (9th Cir. 1982) ("[A]ll that must be shown in order for a question to be 'controlling' is that resolution of the issue on appeal could materially affect the outcome of the litigation in the district court.") and *Bank of N.Y. v. Hoyt*, 108 F.R.D. 184, 188 (D.R.I. 1985) ("'[C]ontrolling' means serious to the conduct of the litigation, either practically or legally . . . .")); *Lawson*, 724 F. Supp. 2d at 169 (finding issue controlling where if the court's determination of the issue was "wrong, the answer to the certified question will prove dispositive of these cases"); *Reynolds*, 2014 WL 201610, at *2 (stating that "[a]n issue is 'controlling' if it is dispositive," and finding issue controlling where "reversing the Bankruptcy Court's ruling with respect to intent would terminate the litigation and result in summary judgment for defendant").[11]

"'The requirement that an appeal may materially advance the ultimate termination of the litigation is closely tied to the requirement that the order involve a controlling question of law.'" *Philip Morris*, 957 F. Supp. at 330 (quoting 16 Charles Alan Wright, *et al.*, Federal Practice and Procedure § 3930 at 432 (2d ed. 1996)). Questions "found to be controlling commonly involve the possibility of avoiding trial proceedings, or at least curtailing and simplifying pretrial or trial." Federal Practice § 3930; *see also In re New Motor Vehicles Canadian Export Antitrust*

[11] *See also* Federal Practice § 3930 ("There is no doubt that a question is 'controlling' if its incorrect disposition would require reversal of a final judgment, either for further proceedings or for a dismissal that might have been ordered without the ensuing district-court proceedings."); *Katz v. Carte Blanche Corp.*, 496 F.2d 747, 755 (3d Cir. 1974) ("A controlling question of law must encompass at the very least every order which, if erroneous, would be reversible error on final appeal.").

Litig., No. MDL 1532, 2004 WL 1571617, at *1 (D. Me. Apr. 20, 2004) (finding that an immediate appeal under 28 U.S.C. § 1292(b) will materially advance the ultimate termination of the litigation as to two parties "because if they are successful on their appeal of this issue, the litigation will terminate as to them"); *Reynolds*, 2014 WL 201610, at *2 ("deciding the instant appeal will materially advance the ultimate end of this litigation because, as with the [controlling question of law] factor, plaintiff's level of intent is dispositive"); *In re Mut. Life Ins. Co. of N.Y. Premium Litig.*, 299 F. Supp. 2d 4, 8 (D. Mass. 2004) (certifying statute of limitations issue for interlocutory appeal where "the resolution of the . . . issue could materially advance the ultimate termination not only of this litigation, but potentially other cases as well").

Here, these two requirements are clearly met as a reversal by the First Circuit of this Court's interpretation of the requirements of the RDSH would terminate this action. As the Court explained in its Order, Omnicare has satisfied the first requirement of the RDSH, namely that the discounts and rebates "are 'made at the time of the sale,' and 'fixed and disclosed in writing . . . at the time of the initial sale.'" Order at 9 (quoting 42 C.F.R. § 1001.952(h)(1)(iii)); *see id.* ("Omnicare has shown, by the contracts themselves, that both the GPO and direct purchase agreements contained and disclosed the entire terms of the agreement between it and Organon. . . . [T]his clears the first element of each safe harbor[.]"). As the Court also acknowledged, the parties agree that no request for documentation regarding the discounts and rebates was made by the government during the relevant time period. *Id.* at 10 ("[T]he parties agree that no such investigation took place during the relevant period."). As such, if, as Omnicare maintains, the RDSH can apply to protect discounts and rebates even where the government does not make a disclosure request during the relevant time period—a question of "pure law" involving "the meaning of a . . . regulation," *So. Orange*, 2016 WL 3064054, at *2—

then it is undisputed that the RDSH would apply to protect the discounts and rebates at issue because, as the Court found, the first requirement of the RDSH has been met here. Indeed, Relators' counsel acknowledged at oral argument that if the discounts and rebates are protected by the RDSH, it "would be the end of the case against Omnicare with regard to . . . the federal claims." June 29, 2016 Motion Hearing Tr. at 18:7-17 (excerpt attached hereto as Exhibit A).[12]

In short, if Omnicare is successful on appeal regarding its interpretation of the purely legal question of the application of the RDSH when no government request has been made during the relevant time period, then Omnicare is entitled to summary judgment dismissing Relators' claims. Accordingly, the issue of the Court's interpretation of the second requirement of the RDSH is a controlling question of law. Further, an immediate interlocutory appeal would materially advance the ultimate termination of the litigation. A decision on this narrow question in Omnicare's favor would avoid the substantial time and expense of a trial in this case. Thus, the first and third requirements for an interlocutory appeal under Section 1292(b) are satisfied here.

B. There Is "Substantial Ground For Difference Of Opinion" On The Controlling Question Of Law At Issue.

There is substantial ground for difference of opinion on the issue of whether the request by the Secretary or a State agency referenced in the RDSH is a necessary condition to the application of the protection of the RDSH, such that if no such request is made during the relevant time period, the discounts and rebates received by the buyer cannot be protected by the RDSH. *See* 42 C.F.R. § 1001.952(h)(1)(iii)(B). Courts have explained that there is "substantial

[12] *Cf. Hoyt*, 108 F.R.D. at 188-89 (explaining that "[a] legal question cannot be deemed 'controlling' if litigation would be conducted in much the same manner regardless of the disposition of the question upon appeal," and denying motion for certification where an intermediate appeal "would likely save neither time nor expense" because "[t]he contours of the trial will be much the same regardless of the disposition of the . . . issue").

ground for difference of opinion" about an issue "when the matter involves 'one or more difficult and pivotal questions of law not settled by controlling authority.'" *Philip Morris*, 957 F. Supp. at 330 (citation omitted); *see also In re San Juan Dupont Plaza Hotel Fire Litig.*, 859 F.2d 1007, 1010 n.1 (1st Cir. 1988). Such is the case here: this Court's Order appears to be the first time that any court has interpreted the RDSH in this particular manner, and there is no controlling regulatory guidance supporting the Court's interpretation. Moreover, "[t]he level of uncertainty required to find a substantial ground for difference of opinion should be adjusted to meet the importance of the question in the context of the specific case." Federal Practice § 3930. Here, because the question is clearly important as its resolution in Omnicare's favor would obviate the need for a trial, certification of the question is warranted even if the Court were to find a relatively low threshold of doubt.

As demonstrated at length in Section I, *supra*, given the plain language of the RDSH (requiring a buyer to disclose the enumerated information only "*upon request* of the Secretary or a State agency," 42 C.F.R. § 1001.952(h)(1)(iii)(B) (emphasis added)), whether the government must issue a request for information from a buyer in order for a buyer to enjoy the protections of the RDSH is a "difficult and pivotal question[] of law" for which there is substantial ground for difference of opinion. This is especially true in view of the extreme practical implications of engrafting such a requirement onto the RDSH, which would make it impossible for a buyer to accept discounts and rebates without automatically being in violation of the law. *See supra* Section I. Further, Omnicare is aware of no First Circuit or other authority that has addressed this issue. *See Natale v. Pfizer Inc.*, 379 F. Supp. 2d 161, 182 (D. Mass. 2005) (certifying interlocutory appeal where, among other things, "binding interpretation from the First Circuit now will clarify this issue and avoid confusion in this circuit").

Indeed, the fact that the interpretation of this requirement of the RDSH is unsettled and that there is substantial ground for difference of opinion on the issue is demonstrated by recent opinions of this Court interpreting the RDSH in ruling on a motion to dismiss. In *United States ex rel. Herman v. Coloplast Corp.*, this Court initially granted a defendant's motion to dismiss after finding that the relators had effectively pleaded an affirmative defense for the defendant by alleging facts such that its arrangement satisfied the AKS's statutory and regulatory safe harbors. No. 11-12131-RWZ, 2016 WL 4483868, at *3 (D. Mass. July 29, 2016); *see* No. 11-12131-RWZ, 2016 WL 4483869, at *1 (D. Mass. Aug. 24, 2016) (discussing July 29, 2016 ruling). However, the day after the Court issued the Order at issue here, it granted the relators' motion for reconsideration in *Herman*, concluding that the complaint lacks allegations suggesting that the defendant met the second requirement of the RDSH, namely "that [the defendant] has provided certain information concerning the discounts to a governmental agency pursuant to its request." *Herman*, No. 11-12131-RWZ, 2016 WL 4483869, at *1 (D. Mass. Aug. 24, 2016). The Court's willingness to reconsider the issue and reverse course in *Herman* demonstrates that this is "difficult and pivotal" question of law that would benefit from review by the First Circuit.

Accordingly, because the requirements set forth in 28 U.S.C. § 1292(b) are satisfied here, immediate interlocutory appeal of this controlling question of law is appropriate.

CONCLUSION

For all of the foregoing reasons, Omnicare respectfully requests that the Court reconsider its Order finding that Omnicare has not satisfied the RDSH and denying Omnicare's Motion for Summary Judgment. In the alternative, Omnicare respectfully requests that the Court amend its Order to include the following statement:

The Court is of the opinion that interlocutory review of this Order under 28

U.S.C. § 1292(b) is appropriate because the Order involves the following controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the Order may materially advance the ultimate termination of the litigation: Is the request by the Secretary or a State agency referenced in the regulatory discount safe harbor ("RDSH") applicable to buyers, 42 C.F.R. § 1001.952(h)(1)(iii), a necessary condition to the application of the RDSH, such that if no such request is made during the relevant time period, the discounts and rebates received by the buyer cannot be protected by the RDSH?

Dated: August 31, 2016

Respectfully submitted,

By: /s/ Aaron M. Katz

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CERTIFICATE OF SERVICE

I hereby certify that the above document(s) filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and that paper copies will be sent to those indicated as non-registered participants on August 31, 2016.

/s/ Aaron M. Katz

Aaron M. Katz